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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/940,558	08/27/2001	Lixiao Wang	S63.2-9482	4996

490 7590 11/20/2003

VIDAS, ARRETT & STEINKRAUS, P.A.
6109 BLUE CIRCLE DRIVE
SUITE 2000
MINNETONKA, MN 55343-9185

EXAMINER

BRUENJES, CHRISTOPHER P

ART UNIT

PAPER NUMBER

1772

DATE MAILED: 11/20/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.		Applicant(s)	
	09/940,558		WANG, LIXIAO	
	Examiner		Art Unit	
	Christopher P Bruenjes		1772	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 September 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2,4 and 7-62 is/are pending in the application.
- 4a) Of the above claim(s) 14-58 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,2,4,7-13 and 59-62 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>6</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

1. Applicant's election without traverse of Group I, Species Ia Claims 1-13 in Paper No. 10 is acknowledged.
2. Claims 14-58 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in Paper No. 10.

WITHDRAWN REJECTIONS

3. The objection to the abstract and the 35 U.S.C. 112 rejections of claims 1-13 of record in Paper #5, Pages 6-7 Paragraphs 11-12 have been withdrawn due to Applicant's amendments in Paper #10.
4. The 35 U.S.C. 102 rejections of claims 1-4 and 6-13 as anticipated by Garabedian of record in Paper #5, Pages 8-9 Paragraph 13 have been withdrawn due to Applicant's amendments in Paper #10.

Art Unit: 1772

5. The 35 U.S.C. 102 rejections of claims 1-6 and 9-13 as anticipated by Saitou of record in Paper #5, Pages 9-10 Paragraph 14 have been withdrawn due to Applicant's amendments in Paper #10.

6. The 35 U.S.C. 103 rejections of claims 7-8 over Saitou in view of Garabedian of record in Paper #5, Pages 11-12 Paragraph 15 have been withdrawn due to Applicant's amendment in Paper #10.

NEW REJECTIONS

Specification

The amendment filed September 24, 2003 is objected to under 35 U.S.C. 132 because it introduces new matter into the disclosure. 35 U.S.C. 132 states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows: "the melt processible poly(tetrafluoroethylene) comprising poly(tetrafluoroethylene) and a copolymer, wherein the copolymer is a fluoro copolymer chosen from the group consisting of a copolymer of tetrafluoroethylene with a perfluoroalkyl vinyl ether, a copolymerization of

Art Unit: 1772

tetrafluoroethylene and perfluoromethylvinylether and a fluorinated ethylene-propylene resin".

Applicant is required to cancel the new matter in the reply to this Office Action.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

7. Claims 1-2, 4, and 7-13 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The limitation that the melt-processible poly(tetrafluoroethylene) comprises poly(tetrafluoroethylene) and a co-polymer, wherein the copolymer is a fluoro copolymer, is new matter because the specification does not teach that the melt-processible poly(tetrafluoroethylene) comprises PTFE and a

Art Unit: 1772

fluoro copolymer. Throughout the specification the melt-processible poly(tetrafluoroethylene) is only PTFE.

Furthermore, the specification on Page 4, lines 23-26 states that the present invention utilizes the findings of WO 00/0871, in which the melt-processible poly(tetrafluoroethylene) taught in that application teaches away from a melt-processible PTFE comprising PTFE and a fluoro copolymer, saying that the properties of the PTFE are lost or diminished when combined with a fluoro copolymer. The only time in the specification that the fluoro copolymer is mentioned on Page 7, lines 22-30 the fluoro copolymer is taught as a polymer making up the first layer that is co extruded to the MP-PTFE and as a component of blend that forms the MP-PTFE of the second layer.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

8. Claims 1-2, 4, and 7-13 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Art Unit: 1772

Regarding claims 1 and 7, the limitation that the "melt-processible poly(tetrafluoroethylene)" comprises poly(tetrafluoroethylene) and a copolymer renders the claim vague and indefinite because it is not understood in light of the specification if the melt-processible poly(tetrafluoroethylene) is a homopolymers or a blend of a homopolymers and copolymer.

Claim 10 is dependent of a cancelled claim.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.

Art Unit: 1772

3. Resolving the level of ordinary skill in the pertinent art.
 4. Considering objective evidence present in the application indicating obviousness or nonobviousness.
9. Claims 1, 2, 4, 9-13, 59-60 are rejected under 35 U.S.C. 103(a) as being unpatentable over Saitou et al (USPN 6,451,005) in view of Lunk et al (USPN 4,859,836).

Saitou et al teach a medical tube comprising a tube that is a catheter, catheter shaft, or catheter balloon (see abstract), comprising a first layer and second layer, wherein the second layer is polytetrafluoroethylene (col.9, 1.56-62). The first layer comprises a fluorocarbon resin including either polytetrafluoroethylene or a perfluoroalcoxy resin (or perfluoroalkyl resin), which includes perfluoroalcoxy vinyl ether with polytetrafluoroethylene, known as PFA, which is a perfluoroalcoxy resin (col.13, 1.48-58). The first and second layers are extruded, therefore the layers are melt-processible (col.14, 1.32-37 and col.15, 1.18-21). The first and second layers are either polytetrafluoroethylene or one of the other thermoplastic resins such as perfluoroalcoxy resin or polyamide. The outer layer flows into the gap between the adjacent windings of the coil and adhere to the periphery of the inner layer. In this way the inner and outer layer contact each other (col.15, 1.7-11). Therefore because the inner or outer layer is the

Art Unit: 1772

first or second layer reversibly, then the polytetrafluoroethylene contacts the inner side of the first layer in one embodiment and the outer side of the first layer in another embodiment.

Saitou et al fail to explicitly teach using a melt-processible or melt-shapeable poly(tetrafluoroethylene). However, Lunk et al teach that poly(tetrafluoroethylene) or PTFE, have very high crystallinity and high molecular weights that they cannot normally be melt-shaped (col.1, 1.31-34). Lunk et al further teaches that a PTFE with crystallinity of at least 50% is blended with a fluoro copolymer having crystallinity below 45% (col.2, 1.47-63). The fluoro copolymer is chosen from the group consisting of a copolymer of tetrafluoroethylene with one or more perfluorinated monomers such as hexafluoropropylene or perfluorinated vinyl ether such as FEP-100, FEP-160 and PFA sold by E.I. du Pont (col.3, 1.65-68 and col.4, 1.1-10). The blend forming the melt-processible poly(tetrafluoroethylene) as shown in Table 1 examples 6-10 have a melting temperature of at least 320°C, a non-zero melt flow index, based on the viscosity, an elongation of at least 10% and a crystallinity of 1-55% (Table 1, cols. 7 and 8). One of ordinary skill in the art would have recognized that when forming a catheter by extrusion using PTFE as taught by Saitou et al, the PTFE must be melt-

Art Unit: 1772

shapeable or melt-processible, and blending a high crystallinity PTFE with a fluoro copolymer having a low crystallinity forms a melt-shapeable PTFE that retains the physical properties of the PTFE as taught by Lunk et al.

Therefore, it would have been obvious to one having ordinary skill in the art at the time the applicant's invention was made to form the PTFE layer of Saitou et al with the melt-shapeable PTFE blend of Lunk et al in order to form a PTFE that is easily melt-shapeable or extrudable and retains the physical properties of the PTFE as taught by Lunk et al. Note the process limitation that the second layer is formed by heating the melt-processible poly(tetrafluoroethylene) to a temperature above its melting point and thermally extruding it to form the second layer and that the first layer and the second layer are thermally co-extruded above their melt temperatures receives little patentable weight because the same article can be made by different processes. Absent the showing of evidence that the article is substantially different based on the process limitation, process limitations are given little weight. Furthermore, in this case the process of extrusion requires that the plastic be melted either prior to entering the extruder or during the extrusion process, either way the plastic is brought

Art Unit: 1772

above the melting point in order to shape the plastic through the extruder.

10. Claims 7-8 and 61-62 are rejected under 35 U.S.C. 103(a) as being obvious over Tomaschko et al (US 2003/0023261 A1) in view of Lunk et al (USPN 4,859,836).

The applied reference has a common assignee with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art only under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 103(a) might be overcome by: (1) a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not an invention "by another"; (2) a showing of a date of invention for the claimed subject matter of the application which corresponds to subject matter disclosed but not claimed in the reference, prior to the effective U.S. filing date of the reference under 37 CFR 1.131; or (3) an oath or declaration under 37 CFR 1.130 stating that the application and reference are currently owned by the same party and that the inventor named in the application is the prior inventor under 35 U.S.C. 104, together with a terminal disclaimer in accordance with 37 CFR 1.321(c). For applications filed on or after November 29, 1999, this rejection

Art Unit: 1772

might also be overcome by showing that the subject matter of the reference and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person. See MPEP § 706.02(1)(1) and § 706.02(1)(2).

Tomaschko et al teach a medical tube (see abstract). The tube has an outer tubular member comprising polytetrafluoroethylene, fluorinated ethylene-propylene, perfluoro(propyl vinyl ether), or combinations thereof (p.2, paragraph 22). An inner tubular member comprising three layers, high-density polyethylene, a tie layer, and polyether block amide, which is a polyamide (p.2, paragraph 25). On the inner surface of the inner tubular member a lubricious liner is added which is comprised of polytetrafluoroethylene (p.2, paragraph 26). Note the method of forming the second and third layers or that the layers are co extruded receive little patentable weight because articles are defined solely by structure, absent the showing of evidence that the method produces a different structural product.

Tomaschko et al fail to teach that the polytetrafluoroethylene of the inner lubricious layer or the outer tubular member is a melt-shapeable PTFE comprising a blend of PTFE and a fluoro copolymer. However, Lunk et al teach that

Art Unit: 1772

poly(tetrafluoroethylene) or PTFE, have very high crystallinity and high molecular weights that they cannot normally be melt-shaped (col.1, 1.31-34). Lunk et al further teaches that a PTFE with crystallinity of at least 50% is blended with a fluoro copolymer having crystallinity below 45% (col.2, 1.47-63). The fluoro copolymer is chosen from the group consisting of a copolymer of tetrafluoroethylene with one or more perfluorinated monomers such as hexafluoropropylene or perfluorinated vinyl ether such as FEP-100, FEP-160 and PFA sold by E.I. du Pont (col.3, 1.65-68 and col.4, 1.1-10). The blend forming the melt-processible poly(tetrafluoroethylene) as shown in Table 1 examples 6-10 have a melting temperature of at least 320°C, a non-zero melt flow index, based on the viscosity, an elongation of at least 10% and a crystallinity of 1-55% (Table 1, cols. 7 and 8). One of ordinary skill in the art would have recognized that when forming a medical tube by extrusion using PTFE as taught by Tomaschko et al, the PTFE must be melt-shapeable or melt-processible, and blending a high crystallinity PTFE with a fluoro copolymer having a low crystallinity forms a melt-shapeable PTFE that retains the physical properties of the PTFE as taught by Lunk et al.

Therefore, it would have been obvious to one having ordinary skill in the art at the time the applicant's invention

Art Unit: 1772

was made to form the PTFE layers of Tomaschko et al with the melt-shapeable PTFE blend of Lunk et al in order to form a PTFE that is easily melt-shapeable or extrudable and retains the physical properties of the PTFE as taught by Lunk et al.

ANSWERS TO APPLICANT'S ARGUMENTS

11. Applicant's arguments regarding the objection to the abstract and the 35 U.S.C. 112 rejections of record have been considered but are moot since the rejections have been withdrawn.

12. Applicant's arguments regarding the 35 U.S.C. 102 rejections of claims 1-4 and 6-13 as anticipated by Garabedian of record have been considered but are moot since the rejections have been withdrawn.

13. Applicant's arguments regarding the 35 U.S.C. 102 rejections of claims 1-6 and 9-13 as anticipated by Saitou of record have been considered but are moot since the rejections have been withdrawn.

14. Applicant's arguments regarding the 35 U.S.C. 103 rejections of claims 7-8 over Saitou in view of Garabedian of

Art Unit: 1772

record have been considered but are moot since the rejections have been withdrawn.

Conclusion

15. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher P Bruenjes whose telephone number is 703-305-3440.

Art Unit: 1772

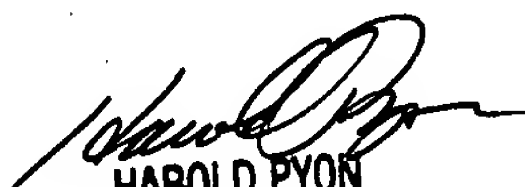
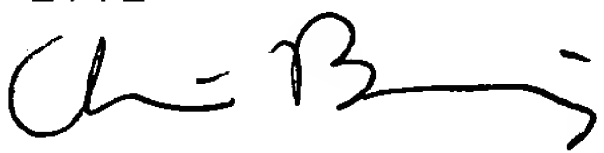
The examiner can normally be reached on Monday thru Friday from
8:00am-4:30pm.

If attempts to reach the examiner by telephone are
unsuccessful, the examiner's supervisor, Harold Pyon can be
reached on 703-308-4251. The fax phone number for the
organization where this application or proceeding is assigned is
703-872-9310.

Any inquiry of a general nature or relating to the status
of this application or proceeding should be directed to the
receptionist whose telephone number is 703-308-0661.

Christopher P Bruenjes
Examiner
Art Unit 1772

CPB
November 14, 2003


HAROLD PYON
SUPERVISORY PATENT EXAMINER
1772

11/14/03